DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2015

G Surgical, LLC
% Karen Warden, Ph.D
President
BackRoads Consulting, Incorporated
P.O. Box 566
Chesterland, Ohio 44026-2141

Re: K142456
Trade/Device Name: GPS™ Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: March 22, 2015
Received: March 24, 2015

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K142456

Device Name
GPS™ Spacers

Indications for Use *(Describe)*

When used as a cervical intervertebral fusion device, the GPS™ Cervical Spacers are indicated for use at one level in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous bone graft and with supplemental fixation systems cleared for use in the cervical spine.

When used as a lumbar intervertebral body fusion device, the GPS™ PLIF and TLIF Spacers are intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) at one or two contiguous spinal levels from L2-S1. These patients should have had six months of nonoperative treatment. These patients may have had a previous non-fusion spinal surgery and/or may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). The device is to be used with autogenous bone graft and in combination with supplemental fixation indicated for lumbar spinal fusion procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date:	29 August 2014
Sponsor:	G Surgical LLC 5757 Central Avenue, Suite G Boulder, CO 80301 USA Tel.: 720.638.4287 Fax.: 720.638.4289
Contact Person:	Don Grafton, Managing Director
Trade Names:	GPS™ Spacers
Common Name:	Interbody fusion device
Device Classification	Class II
Classification Name:	Intervertebral body fusion device
Regulation:	21 CFR 888.3080
Device Product Codes:	ODP, MAX
Device Description:	The basic shape of the Cervical and Lumbar GPS™ devices is a structural column having upper and lower implant openings and a central cavity for autograft bone. The cervical devices have a have a "B" shaped cross-section. The PLIF devices are rectangular having a pyramidal anterior surface. The TLIF device cross-section is curved having a wedged leading face. For all devices, surface teeth assist in the seating the implant between the vertebral bodies. Each device type is available in a variety of size and angulation combinations to accommodate the diversity in patient anatomy.
Intended Use:	When used as a cervical intervertebral fusion device, the GPS™ Cervical Spacers are indicated for use at one level in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous bone graft and with supplemental fixation systems cleared for use in the cervical spine. When used as a lumbar intervertebral fusion device, the GPS™ PLIF and TLIF Spacers are intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) at one or two contiguous spinal levels from L2-S1. These patients should have had six months of nonoperative treatment. These patients may have had a previous non-fusion spinal surgery and/or may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). The device is to be used with autogenous bone graft and in combination with supplemental fixation indicated for lumbar spinal fusion procedures.
Materials:	The GPS™ Spacers are manufactured from polyetheretherketone (PEEK) per ASTM F2026 (VESTAKEEP® i4 R, Evonik Polymers Technologies GmbH). Integral marker pins are manufactured from tantalum according to ASTM F560.
Predicate Devices:	Primary: IMPIX Interbody Devices (Medicrea™ Technologies – K083798) Reference: MC+ (LDR Spine USA – K091088) BAK/C (CenterPulse Spine-Tech – P980048) Eminent Spine Interbody Fusion System (Eminent Spine – K090064) Lumbar I/F Cage® (DePuy AcroMed, Inc. – P960025)

Performance Data:

Mechanical testing of the worst case GPS™ Spacers was performed according to ASTM F2077 and included static and dynamic compression and static and dynamic torsion. The subsidence properties were evaluated according to ASTM F2267. Expulsion testing was performed.

The mechanical test results demonstrate that the GPS™ Spacer performance is substantially equivalent to the predicate devices.

Technological Characteristics:

The GPS™ Spacers possess the same technological characteristics as the predicate devices. These include:

- performance (as described above),
- basic design (hollow structural frame),
- material (PEEK polymer and tantalum), and
- sizes (widths, lengths and heights are within the range(s) offered by the predicate).

Therefore the fundamental scientific technology of the GPS™ Spacers is the same as previously cleared devices.

Conclusion:

The GPS™ Spacers possess the same intended use and technological characteristics as the predicate devices. Therefore the GPS™ Spacers are substantially equivalent for their intended use.